

REACH Alliance Q&A

(1) Questions indicating raise of understanding by industry

(2) Questions for interpretation

(3) Questions fundamental for the inorganic sector

Disclaimer:

This document has been produced for information purposes only and is not in any respect a legal interpretation of the Regulation (EC) 1907/2006.

1. PRE-REGISTRATION

• What will happen if we miss pre-registration? Can we proceed straight to registration? Can a company still market the substance? (1)

If a company fails to pre-register within the applicable deadline, or does not wish to preregister, it will have to suspend its activities involving the substances concerned and register the substances without delay prior to starting to manufacture or import this particular substance after 1 December 2008.

If a company continues manufacturing or importing a substance after 1 June 2008 and if it did not pre-register by 1 December 2008, it would be in breach of the REACH Regulation. This also means that the downstream uses of these substances may be at risk.

• Can a company with various legal entities submit a common pre-registration, registration at the same time or does it have to do this entity by entity? (1)

No, each legal entity of a Company has to pre-register and register each substance manufactured or imported.

• Could a Consortium make the (pre)-registration for its members? (1)

No, the pre-registration and the registration must be done by each Legal Entity. A Consortium can prepare the pre-registration and the registration of its members but neither pre-register nor register.

• **Does the EU provide any documents /templates for pre-registration? (1)**

The pre-registration will be done via IUCLID 5 and REACH-IT.

• **Does pre-registration finally decide on the status of the substance? (1)**

Due to the high number of pre-registration dossiers, it is expected that the Agency will not have the capacity to check the status of the substance. Therefore, it is likely that the SIEF will be responsible to decide on the status of the substance.

• **Where and how do I need to pre-register? (1)**

Pre-registration takes place when the company has submitted electronically to the ECHA the required information on a substance. This information includes:

- The name(s) of the substance specified in section 2 of Annex VI, i.e.
 - ✓ the names in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature or other international chemical name(s);
 - ✓ other names (usual name, trade name, abbreviation);
 - ✓ European Inventory of Existing Commercial Chemical Substances (EINECS) number (if available and appropriate);
 - ✓ Chemical Abstract Service (CAS) name and CAS number (if available);
 - ✓ other identity code (if available);

- The name and address of the pre-registrant and the name of the contact person and, where appropriate, the name and address of a third party representative whom the pre-registrant has selected to represent him for all the proceedings involving discussions with other manufacturers, importers and downstream users (Article 4);

- The envisaged deadline for registration and tonnage band;

- The name(s) of other substance(s) for which the available information is relevant for performing adaptations to the testing requirements, i.e. use of results from (Q)SAR models (section 1.3 of Annex XI) and read-across approach.

The online submission must be done via the REACH IT system, i.e via a web tool or via the IUCLID 5 software.

• **Should a substance that does not have to be registered (e.g. coal) be pre-registered? (1)**

No

• **How do we know into which tonnage band a substance we use or produce in the EU will fall? (1)**

Calculation of the tonnage for the registration of phase in-substances that have been preregistered

In the case of a phase-in substance that has been imported or manufactured for at least three consecutive years, the quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years. This value is to be used for the purpose of pre-registration, unless it is estimated that by the time of the pre-registration deadline the volume will be higher than the next tonnage band. In the case that the same registrant manufactures and/or imports the same substance in different sites (i.e. in different Member States) then the volume of substance to be registered is the total of the volumes of the substance manufactured and/or imported in the different sites, because the sites are not separate legal entities.

Example:

If company Y wants to register a phase-in substance in April 2010, the tonnage is first calculated for the years 2008 (calculated as the average over 2005-2007), 2009 (calculated as the average over 2006-2008) and 2010 (calculated as the average over 2007-2009).

The highest tonnage calculated for the years 2008, 2009 and 2010 then has to be used to determine the deadline for registration according to Article 23. This provision has been put in place to avoid situations where a sudden increase in demand would lead to the impossibility to comply with the registration obligations.

The tonnage for 2010 (calculated as the average over 2007-2009) could then be used in the registration dossier.

In order to be able to calculate the amount of a substance in a preparation, the total volume of the preparation is multiplied by the fraction of the constituent substance. This value can for example be obtained from the safety datasheet of the preparation. When only a range of concentrations of a substance in a preparation is available then the highest value is chosen to be the content of that substance in that preparation for the purpose of calculating the volume of substance.

In the case of articles which contain a substance that is intended to be released under normal or reasonably foreseeable conditions of use, then:

- If the weight by weight content of that substance is known, then this value is multiplied by the total mass of the manufactured and/or imported article; or If the weight of substance per unit article is known then this value is multiplied by the total number of imported articles.

This volume is then used in order to decide whether a registration must be submitted, what the information requirements are that have to be fulfilled (in accordance with the different annexes) as well as, in the case of phase-in substances, decide when the registration of the substance has to be made.

For the transitional regime the tonnage to take into account is the highest tonnage manufactured and/or imported after the 1st June 2007 (taking in to account the calculation method explained above). If the level is exceeded once after 1 June 2007 this determines the tonnage band in which the substance has to be registered.

Example:

If the volume of Company Z is 120 tonnes (calculated as 3 years average) in 2009 and decreases to less than 100 tonnes after that, Company Z will still have to register in the 100 – 1000 tonnage band, registering ultimately 31 May 2013.

If the volume of Company V is 600 tonnes in 2007, 900 tonnes in 2008, 1400 tonnes in 2009 and 2000 tonnes in 2010. The "3 year-average" tonnage in 2010 is 966 tonnes/year, but the "3 year-average" tonnage in 2011 is 1433 tonnes/year. In this case the company V will have to register the substance in 2011.

In a similar way if a substance is used both as a non-isolated intermediate and/or as an on-site isolated intermediate and/or as a transported intermediate (provided that the relevant requirements in the legal text for intermediates are fulfilled) and is also used for other purposes, then the quantity of substance covered by the reduced registration requirements for intermediates (or exemption from REACH for non-isolated intermediates) does not have to be counted for the purpose of the registration obligation of the remainder of the substance. However, the potential registrant can also choose to make only one registration covering the total tonnage, in which case the use as an intermediate must be included in the calculation of the tonnage band and the CSR incl. development of ES and documentation of adequate control (which should not be difficult when the strict controlled conditions apply).

2. REGISTRATION (RIP 3.1/3.4)

- **Could a “consultant” or an “Association” take the role of Lead Registrant? (1)**

No, the Lead Registrant must be one of the registrants. However, the official representative for the lead registrant may be a consultant if he has been mandated by the legal entity to act on its behalf.

- **For companies with several different legal entities, will they be charged for registering each substance in each entity? (1)**

Yes

- **Do I have to register the substance or the use of the substance? (1)**

The substance (mentioning the identified uses in the CSR if needed)

- **Is the registration number linked to the substance, to the company, or both? (2)**

Not yet determined by the EC.

- **Do I have to register as a trader? (1)**

Trader does not exist in REACH. If a trader is an importer, yes he has to register. If a trader is a distributor, no he has to pass the information throughout the supply chain.

- **If you produce in “tolling” conditions, who should then register, the owner or the operator?**

The manufacturer has to register.

- **Is mechanical equipment (e.g. engines) up for registration? (3)**

Mechanical equipment should be dissociated into its various components. Most of them would probably be considered as articles but some could be regarded as preparations (e.g. battery???)

- **Can a "category registration" be made, i.e. the consortium prepares a CSR for a category of substances (e.g. several compounds of the metal). The consortium members then use this single CSR which covers several compounds of the same metal to register their individual substances? (2)**

No registration by category but by substance. For the CSR???, I assume that if the CSR is covering the substance to be registered you can use it in the several registration

dossiers....

• Do “unintentional impurities” (from ores or secondary raw materials) have to be registered?

What if they are CMR’s? (1)

No, the Classification & Labelling of the substance must be notified to the Agency as of 1 December 2010. If an impurity meets the criteria for classification and is present above a certain threshold, the substance itself shall be classified and labelled, and thus this classification and labelling shall be notified to the Agency as of 1 December 2010.

• Do substances that were already registered under the "existing substances" regulation have to be registered again? (1)

Yes. However, a notification in accordance with Directive 67/548/EEC shall be regarded as a registration and the Agency shall assign a registration number by 1 December 2008.

• For the M/I, does pre-registration automatically mean registration? Does this mean that registration bears on the pre-registered substances, or is it possible to register as UVCB a “sum” of the pre-registered substances (which have EINECS)? (2)

No, there is no obligation to register a substance that has been pre-registered. There is no clear answer to the second part, although this approach is followed for preparations.

• If a substance, metal or metal compound, has already been registered at the Agency by someone else, do you still have to register it? (1)

Yes (except in the case of substances in articles – see art. 7)

• Do we have to register at the ECHA the substances that we import? (1)

Yes, unless the substances imported into the EU have been first exported from the EU or is below 1 tonne or is exempted from registration..

• No data, no market: does this mean that we have to register all substances that we can conceive of importing/manufacturing in the future? What happens if we start working with a new “material” that is phased-in and registered by somebody else after the time limits of registration have passed? We may import a substance after the end of pre-registration. Can we pre-register in anticipation of this to take advantage of phase-in timing? (1)

Companies which manufacture or import substances, on their own or in preparations, or

produce or import articles containing substances in quantities of less than 1 tonne per year but which are planning to exceed the 1 tonne threshold after 1 December 2008 will also be entitled to pre-register and thus benefit from the transitional period.

The pre-registration period will then start right after the first manufacturing or import exceeding the 1 tonne threshold, and will end 6 months later. However pre-registration will only be possible if it can be submitted 12 months before the relevant deadline for registration. First time manufacturers or importers will therefore have to submit their preregistration by 30 November 2009, 31 May 2012 or 31 May 2017, whichever is relevant in view of their tonnage threshold.

• Do we have to provide information on the downstream use of materials that we sell but neither produce nor import? (1)

Yes, the distributor is obliged to ensure a good communication throughout the entire supply chain.

• Does registration have to take into account all tonnages placed on the market today? (1)

Yes, the tonnage band should be calculated as an average over the last three years. However, if in the next years, the manufacturer or importer exceed the tonnage bands (>10, >100, >1000T), then additional information would have to be submitted.

• Will the Agency accept registrations from a non-EU entity that exports into the EU? (1)

No, the registrant has to be based in EU (EU manufacturer, Importer or Only representative appointed by a non-EU manufacturer)

• What happens in the case of a mixture of existing substances that are registered? Must the mixture also be registered? (mixture: no chemical reaction) (1)

No a preparation has not to be registered. A manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.

• Is the EU REACH System (registration) also of relevance for OECD countries? (1)

NO

• Will Switzerland, Iceland, Lichtenstein and Norway be considered as part of the EU for registration purposes? (1)

According to the corrigendum (published on 29 May 2007) of the REACH Regulation (EC) 1907/2006, Iceland, Lichtenstein and Norway (EEA countries) will be considered as part of the EU for all REACH requirement, including Registration.

Importers of a substance from Switzerland will have the same obligations under REACH as any other importer.

• If I produce substances abroad, can I expect my customer to register these substances for the EU? Example: we use 31 metals or metal compounds. How can we check? (2)

Yes, the importers are obliged to register the substances that they import above 1 tonne per year. As non-EU manufacturer, you have two solutions to ensure that you will maintain your business in EU:

-Communicate with all the EU importers to ensure that they will comply with their REACH obligations.

-Appoint an Only representative (art. 8) to take over the role of the importer in REACH and comply with all the REACH requirements.

3. EVALUATION (RIP 4.1/4.2)

• What is the timeline for dossier evaluation? (1)

- 1 December 2012 for all registrations received by 1 December 2010

- 1 June 2016 for all registrations received by 1 June 2013

- 1 June 2022 for all registrations received by 1 June 2018

4. AUTHORISATION (RIP 3.7.-3.9.-4.3/4.5.)

• What could be the links or relationship between “Authorisation” and “Restriction” for one and the same substance? (2)

The procedure of setting substances on Annex XIV (substances for authorisation) starts with the Annex XV dossier, under which certain uses of substances will be restricted.

There is a relation between the restriction and the authorisation procedure under REACH.

• Ores and concentrates: not up for registration but potentially for authorization. When should the Agency be informed?

There is no requirement to inform the agency about Registration or Authorisation of ores & ore concentrates. If an ore or ore concentrate is listed as a candidate for Authorisation, the Agency will publicise the listing and industry will have several opportunities to respond. The first list of candidate substances for Annex XIV shall be released by the Agency by 1 June 2009.

There is a separate requirement to notify the Agency of the Classification & Labelling of ore & ore concentrates that meet the criteria for classification as dangerous as of 1 December 2010

• What is the difference if they are pre-registered?

Ores & ore concentrates are exempt from Pre-Registration if they are not chemically modified. Pre-Registration of an exempt substance does not bring any advantage.

• Likely to be on the Authorisation list? (3)

No, because there are no specific EINECS entries for ores & ore concentrates for the moment, and because the Member States together with the Commission have to decide in a very complex process if a substance should be listed in Annex XIV (substances for authorisation). It is much more likely that impurities found in ores & ore concentrates could be listed for Authorisation. When this happens, there are several opportunities to introduce an exemption for the case of ores & ore concentrates.

• What is the procedure if the SVHC for substances that have already been through the RM procedure under the current system? (2)

There will most likely not become (first) candidates for authorisation.

• Do the specific applications/uses of the SVHC accepted/covered in the RM have a « granted » Authorisation? (2)

Further information is needed.

• Is a manufacturer of a substance, for example a metal or metal compound, required to submit a substitution plan for the uses of his/her substance? Or is this down to the downstream user? (3)

If alternatives are identified by the manufacturer, it is technically his duty to submit a substitution plan. However, in practice the manufacturers may not know enough about the alternative(s) to propose such a plan and he would need to work closely with the

downstream users.

It could be both (see Art. 62). It is the task of the applicant to come up with a substitution plan. Both, manufacturers and downstream users can apply for an authorisation.

• Can you jointly apply for Authorisation (joint application – Consortium)? (1)

Yes, the most practical and efficient approach would be for the members of a Consortium to make a joint application. Yes, see Art. 62

• If Authorisation is granted, does it apply to all the M/I/DU concerned? (1)

A granted authorisation applies to all of the M/I/DU who have made the application.

Subsequent applicants can refer to appropriate parts of the previous application provided they have the permission of the previous applicants, but they are not automatically covered by the previously granted authorisation.

Only those who have applied for an authorisation. But, subsequent applicants may refer to the appropriate parts of the previous application submitted in case of the permission of the previous applicant.

• From the time the substance is on candidate list until Committee opinion, do we have to withdraw the substance from the market? (1)

No, withdrawal of a substance would only result from a formal restriction or a failed application for authorisation, and then only after a specified period of time to allow a substitution plan to be put into effect.

NO!!! You are allowed the substance until the so-called “sunset date” has been reached and no authorisation could have been gained. The sunset date is only applicable to substances listed in Annex XIV, but not to the substances in the candidate list.

• What is the status of R&D plans in connection with Authorisation? (1)

If suitable alternatives do not exist, R&D plans could form part of a substitution plan, being necessary precursor to the identification of suitable alternatives.

• Is the submission of an R&D plan mandatory in connection with Authorisation based on « SEA » or on « adequate control »? (1)

This is not entirely clear. Although R&D is referred to under the mandatory information requirements of Article 62.4(e), the precise wording is “...including, if appropriate

information about any relevant R&D activities by the applicant”.

• Do « Third Parties » have to provide evidence that the alternatives are suitable? (Not just having an alternative)? What are the requirements of proof for this evidence? (2)

In theory there should be proof of suitability, but the only reference in the text of REACH is in Article 64.4(b) where the SEA Committee is required to make “an assessment of the ...availability, suitability and technical feasibility of alternatives”. RIP 3.9 should elaborate on this question of proof.

• As a “one product company” are we expected to have a Substitution plan using a Substance that we do not manufacture and which may be a competitor’s product? This raises several legal issues under Competition Law and other... (1)

In theory yes, but in practice you are unlikely to acknowledge that there is an alternative substance. If you do acknowledge that there is an alternative, you would be expected to work with the downstream users on a substitution plan. On the other hand you could submit an incomplete authorisation application and leave it to the competition or the DUs to submit a substitution plan.

• Priority criteria for authorisation includes « dispersive use »: Is there a working definition for « dispersive use »? Is it clear that « dispersive use » is not the same as widespread use? (2)

Yes, this has been pointed out in the SEG meeting and further comments related to RIP 4.3/4.5

• What is the difference in procedure between a Restriction procedure and an Authorisation procedure? (1)

• Is « use as an intermediate » an exempted use from Authorisation? (1)

Intermediates are not subject to authorisation (see Art. 2 (8))

• What is the timing of any changes in the C&L of a substance to be implemented to its Authorisation? (1)

At first, a member state or the Agency has to propose a substance to be set onto the candidate list. This process starts with the Annex XV dossier. Stakeholders and third parties are allowed to comment. If the substance finally became a candidate for

authorisation, then, based on the criteria for prioritization (will be defined in RIP 4.3/4.5) and substance can be set onto Annex XIV. This is where substances subject to authorisation are listed.

• **Will the Authorisation be dropped automatically once a substance is no longer CMR 1-2? (1)**

This is unlikely. The scenario does not appear to have been allowed for in the Regulation. The procedure for a withdrawal from Annex XIV in case of de-classification is actually under discussion in RIP 4.3

• **Period after Authorisation, is it suitable? (1)**

• **Is there a limit for the Authorisation to be given more than once? (1)**

Authorisations will be time-limited, the time being decided on a case-by-case basis, and can be granted repeatedly if no suitable alternatives can be identified.

• **Can there be any M/I that needs to be continuously granted by an Authorisation? (1)**

This is unlikely to happen, since the procedure requires time-limited authorisations.

• **Some substances exempted from registration could still fall under Authorisation. A MS or the Agency would have to prepare an Annex XV dossier. Do they have to involve the producers/importers of the substances in the preparation of the Annex XV dossier? (1)**

No involvement in the preparation of Annex XV dossiers. Industry comes into play after the finalisation of Annex XV dossier. They can then oppose to stop the procedure of setting the substance on the candidate list.

5. NOTIFICATION OF CLASSIFICATION AND LABELLING, GHS AND MSDS (RIP 3.2, 3.3, 3.6)

• **What is the procedure in cases where no toxicity data exist and you need to notify the classification of a substance? (1)**

Data needs prescribed by REACH need to be filled. Where no data exist, they need to be generated. For vertebrates testing, permission is needed from the Agency. The collected data can then be used to classify the substance.

For substance falling outside the scope of registration, authorisation, classification is

based on the available data! There is no obligation under REACH to generate such data.

• If there is no agreement on classification, in the EU, the ECHA will register the various entries.

In the EU-GHS, the system works on a “first-come, first-served” basis: the first 2 or more companies notifying Classification will be considered as prima facie. The next ones with a different entry will have to provide justification. What are the recommendations for C&L: notify asap? (2)

It is recommended to base any classification proposal on a good scientific basis. Any classification proposal will need to be justified. Where differences appear, the different registrants will be asked to come to a harmonised classification.

REACH says that in case of various entries, the notifiers shall make all possible efforts to agree on a common entry. This shall be discussed in the SIEF and is indeed one of the two objectives of the SIEF. Where registration is not required, there will be no SIEF and therefore the possible agreement should be sought outside the "SIEF rule".

Also, if the substance is regarded as of high concern by a Member State, this Member States may request the harmonisation by the EU Competent Authorities.

However, the GHS draft locked in the first classification agreed by 2 or more parties. This is a serious issue that should be resolved during the co-decision procedure for GHS !!!

• Do we need to update our SDS at midnight on 31 May 2007? (2)

This has been discussed at the last CWG meeting (March 2007) where Industry asked for a pragmatic and flexible approach to enforcement, stressing the pure administrative nature of the changes (CEFIC). This has been supported by several Member States. Conclusion was that the content, not the format of the SDS is the priority for the enforcement and that the changes required by REACH i.e. the changed order of chapters 2 and 3 and the addition of the e-mail address can be introduced when (substantial) changes/up-dates are made of the SDS. A substantial change could be the classification according to GHS or the addition of exposure scenarios. The changes required by REACH should however be introduced before the first dead-line for registration on 1 December 2010.

6. CHEMICAL SAFETY REPORT (RIP 3.2.)

- **How many Exposure Scenarios will be needed in general for a substance (10, 100, 1000)? (2)**

This is difficult to say; it depends on the substances and its specific uses. Eurometaux is developing generic exposure scenarios which are aimed to cover as much as possible uses at the same time, so as to reduce the number of exposure scenarios.

- **What about the foreseeable non-compliance of the consumer with RMMs (most will not read the instructions)? Does this have to be considered? (2)**

Risk management measures are generally not intended for the consumers. If exposure and so risks to consumers need to be managed, it will be up to the producer of these articles to ensure that the exposure is limited during the use of the substance by the consumer. For example, coatings could be applied to a metallic surface where dermal exposure is to be prevented to the metal.

- **How does a M/I get exposure data from end-of-life processes (e.g. copper smelters, waste processes, recyclers)? (2)**

By ensuring good communications before and after the registration deadline: During the preparation of the chemical safety report, M/I need to set-up good communications with the downstream users so that exposure data can be collected from the downstream users and end of life. From the final chemical safety report, the M/I will extract the relevant exposure scenarios and add these to the MSDS. The DU when receiving the MSDS needs to check the exposure scenario relevant for his activities. Where the exposure assessment is too high, the DU communicates this back to his supplier who passes the relevant info up the supply chain to the M/I so that the latter can update the exposure assessment and exposure scenario.

- **Where in the production chain does the risk calculation stop? When the substance is turned into an article? (1)**

Risks due to exposure to the substance are assessed for the ENTIRE life cycle of the substance. This includes when used in an article and when disposed of (end of life).

- **What about ES coming from other sources of emission than those caused by activity in charge of the dossier (e.g. metals from fossil fuel burning)? (3)**

The chemical safety report addresses only the intended uses of the tonnage marketed.

Metals released during fossil fuel burning needs to be addressed by the exposure scenario for fossil fuels and are so part of the fossil fuel chemical safety report.

7. SIEF (RIP 3.4.)

• What are the differences between SIEF and consortia formation? (1)

The SIEF is an obligation described in REACH (see art. 29), a consortium is a voluntary form of cooperation of the Industry.

• What is the benefit of entering a SIEF? (1)

You have no choice to enter or not in a SIEF. The participation to a SIEF is mandatory.

• Will the ECHA play a role in SIEF and consortia? (2)

No, it is up to the Industry to organize itself.

• Can an « only representative » represent more than one non-EU manufacturer? (1)

It should be noted that the “only representative” would not be covering the registration duties for the same substance manufactured by another non-EU manufacturer; if the importer obtains the substance from a number of non-EU sources he may still have to act as registrant. The question is still under discussion in the Commission.

• Who decides what are acceptable quality and relevant tests (studies)? In particular in a SIEF? (2)

The registrants decide on what is relevant or not. Some mechanisms to (e)valuate the existing data are under development in RIP 3.4.

• Web site addresses for SIEFs? (1)

No website addresses. As soon as you have pre-registered you will be in on a list with the other pre-registrants of the “same substance”. After this up to the industry to organize itself.

• Are there any specific rules about how the costs have to be shared within a consortium/SIEF? (2)

REACH mentioned that the “participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non

discriminatory way". In case of disagreement, the default mechanism will be "equal share". RIP 3.4. is actually developing some guidance on how to share the cost in a "fair, transparent and non-discriminatory way". This guidance will be available after the EIF.

8. IDENTIFICATION OF SUBSTANCES (RIP 3.10.)

• If one and the same substance is manufactured on the one hand, and naturally occurring on the other, the first one has to be registered, but not the second one. (3). E.g.: Diamonds fall under the heading "minerals not chemically modified", but what about synthetic diamonds that do not occur naturally?

Minerals, ores, ore concentrates (etc.) which occur in nature, if not chemically modified, are exempted from registration according to Annex V. Although this is not explicitly the case for their equivalent produced by a manufacturing process (at least in the REACH Regulation) RIP 3.10 clearly states that provided the composition is similar and the toxicity profile identical, both will be identified as the same substance. However it is added that this "does not necessarily mean that the legal requirements (e.g. exemptions from registration) are the same". The review of Annexes IV & V by the Commission could clarify this aspect.

• Does the impurity ruling for mono- and multi-constituent substances also apply, e.g. 10% in the case of substances of high concern? (2)

RIP 3.10 states that although only impurities present in a concentration =1% should be specified, impurities that are relevant for classification shall always be specified (e.g. any carcinogen category 1 shall be specified in present in concentration above 0.1%).

• What if the "impurity" has a valuable function (for the user), is specified in the contract, and payment is requested? (2)

In the RIP 3.10, an impurity is defined as follows: "unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance it was not intentionally added. Also, an impurity would be present in quantity below 10%. However, a manufacturer/importer may decide to register his substance as multi –constituents substances, the "valuable impurity" being then identified as a valuable constituent.

• Is there a possibility to justify reasons for deviation from the 80% rule? What kind of justification would be acceptable? (2)

RIP 3.10 clearly states that the 80% rule is a rule of thumb and that deviation is possible but has to be justified.

Examples of justification:

For mono-constituent substances :

- the main constituent is < 80% but the substance can be shown to have similar physicochemical properties and the same hazard profile as other mono-constituent substances with the same identity that fulfill the 80% rule.
- The range of concentrations for the main constituent and the impurities overlap the 80% criterion and the main constituent is only occasionally 80%.

For multi-constituent substances:

- a substance contains two constituents, one at 85% and another at 10%, the balance being impurities. Both constituents contribute towards and are essential for the desired technical effect of the substance. In this case, despite one constituent being present at > 80%, the substance can be described as a two-constituent substance.

• MCS: if a constituent is never supplied separately to the bulk substance, would it have to undergo tests individually, or is it OK to test it as part of the MCS only? (2)

REACH requires the registration of a substance as produced. Therefore you may test only the bulk substance. However, you are offered the possibility to register constituents of a substance separately as there is no need to test the substance as such, if its hazard profile can be sufficiently described by the information of the individual constituents.

• How do you deal with a substance containing >80% one substance and >10% of another substance? Will this be considered a mono-constituent substance, or can you choose how to consider it? (2)

In accordance with the above example (see box), you may choose how to consider it.

• Scrap and waste: Is scrap defined? Not considered as a waste? (3)

Waste is clearly excluded from the scope of REACH. However, the waste / not waste issue is not a matter for REACH. This issue is currently discussed under the revision of the

Waste framework Directive where the concept of by-product will be introduced and defined. By-products placed on the market are within the scope of REACH.

• **Difference between the 2nd approach MCS (name mixture) and a preparation (mixture in GHS)? Difference between a preparation assessed on its own and a first approach MCS? (2)**

RIP 3.10 indicates that the difference between preparation and multi-constituent substance is that a preparation is gained by blending of two or more substances without chemical reactions, while a multi-constituent substance is the result of a chemical reaction (RIP 3.10 acknowledges that this is not the case for minerals, which can be treated either as mono- or multi-constituent substances).

• **Could you provide an example of each of the following categories: substance, preparation, multi-constituents substance, mono-constituent substance, alloy, article, intermediate? (1)**

Substance:

- Mono-constituent: Calcium oxide, Copper, Chlorite, Quartz, Boric acid
- Multi-constituents: Cement-clinker
- UVCB: feldspar, bentonite, kaolin

Preparation: paint, ink, milk of lime, mineral slurries

Alloy: an alloy is a special preparation (e.g. steel)

Article: a plaster Board, a sheet of paper, a ceramic plate

Intermediate: In some paper mill, lime is produced in-situ and then converted into calcium carbonate. In this example, lime is an intermediate.

9. REACH IT (RIP 2)

• **IUCLID 5 could run on a PC, but what is the size of IUCLID 5? (1)**

- The installation kits are 70-100 MB
- The EC inventory is about 20 MB
- The full set of reference substances (with structure images) are ca 500 MB
- The database size needed for the application depends of course on the amount of data that needs to be stored.
- IUCLID stores attachments inside the database, the size of a substance or dossier is around 2 MB + the size of the attachments.

• **When you submit your dossier, you need an ID and password; when does the password**

arrive with pre-registration number? (1)

The person who submits a dossier is not necessarily the same as the person who takes care of Pre-registration. This means that there will be a 'User Account creation process' to take care of this. I did not see the requirements of the REACH-IT system for creation of a User Account

• RMM will be obligatory with REACH; will standard phrases be developed for this, comparable with risk and safety phrases? (2)

Yes

• What will be visible to whom in REACH IT? Can the registrants check/consult the part of the dossier submitted jointly? (1)

No

10.READ-ACROSS/CATEGORIES (RIP 3.3)

• Many metals underwent formal or voluntary RA under the ESR, and many tests were waived under this programme. Do those that were waived remain valid, especially for C&L requirements for <100T, where no waiving can be provided officially under REACH? (3)

Where waiving was previously agreed, the basis for this will need to be checked with the criteria for waiving under REACH. Arguments for waiving of testing under REACH are described in Annexes VII to Annex X, second column of the tables and in Annex XI. These criteria for waiving apply for all substances produced > 10 T/yr.